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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/973,265   | 10/09/2001  | Ashok Rampal         | RLL-124CIPUS        | 8161             |
| 26815  | 7590        | 04/18/2006           | EXAMINER            |                  |
| RANBAXY INC.<br>600 COLLEGE ROAD EAST<br>SUITE 2100<br>PRINCETON, NJ 08540 |             |                      | LUKTON, DAVID       |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1654                |                  |

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/973,265             | RAMPAL ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | David Lukton           | 1654                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 January 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,6-8,10-16,20-27 and 30-47 is/are pending in the application.
- 4a) Of the above claim(s) 8,15,16,20 and 30-47 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,6,7,14,21-24 and 27 is/are rejected.
- 7) Claim(s) 10-13,16,20,25 and 26 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are; a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

Pursuant to the directives of the response filed 1/13/06, claims 5, 9 and 29 have been cancelled, and the following claims amended: 1, 6, 7, 10-16, 23-27. Claims 1-3, 6-8, 10-16, 20-27, 30-47 are now pending.

Applicants' arguments filed 1/13/06 have been considered and found persuasive in part. The rejection of claim 27 as anticipated by Ballester Rodes ('875) is withdrawn. Claims 8, 15, 16, 20, 30-47 remain withdrawn from consideration. Claims 1-3, 6, 7, 10-14, 21-27 are examined in this Office action.

◆

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending application Serial No. 09/086,224. Although the conflicting claims are not identical, they are not patentably distinct from each other; there is overlap of the claimed compositions. [This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented].

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

◆

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 6, 7, 14, 21-24, 27 are rejected under 35 U.S.C. §102(e) as being anticipated by Lee (USP 6,228,400).

As indicated previously, Lee discloses compositions in which a composition comprising omeprazole is coated on a neutral core, and wherein the composition comprises a water-insoluble polymer.

Applicants have argued that Lee does not disclose PVP. However, this is disclosed, for example, at col 3, line 21, col 4, line 17, and col 5, line 47.

The rejection is maintained.



Claims 1-3, 6, 7, 14, 21-24, 27 are rejected under 35 U.S.C. §102(e) as being anticipated by Bergstrand (WO 96/01623).

Bergstrand discloses compositions in which a composition comprising omeprazole is coated on a neutral core, and wherein the composition comprises a water-insoluble polymer. Core materials are discussed at page 7, line 21+.

In response, applicants have required that the claimed compositions contain PVP. However, the reference discloses this, for example, at p. 10, line 16 and page 12, line 30. The rejection is maintained.

◆

Claims 1-3 are rejected under 35 U.S.C. §102(b) as being anticipated by Lovgren (USP 4,786,505).

As indicated previously, Lovgren discloses a composition comprising omeprazole and PVP. In response, applicants have amended claim 1 to require the presence of PVP. However, Lovgren discloses this. See, e.g., the following locations: col 8, line 39; col 9, line 27, col 11, line 53, col 12, line 11 and col 16, line 64.

The rejection is maintained.

◆

Claims 1-3, 6, 7, 14, 21-24, 27 are rejected under 35 U.S.C. §102(e) as being anticipated by Henriksen (USP 6,391,342).

As indicated previously, Henriksen discloses compositions in which a composition comprising omeprazole is coated on a neutral core, and wherein the composition comprises a water-insoluble polymer which can be cross-linked PVP.

Applicants have amended the claims to require PVP. However, this is disclosed, e.g., at col 7, line 9, and col 8, line 7:

◆

The following is a quotation of 35 U.S.C. §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-3, 6, 7, 14, 21-24, 27 are rejected under 35 U.S.C. §103 as being unpatentable over Chen (USP 6,096,340).

Chen discloses compositions in which a composition comprising omeprazole is coated on a neutral core, and wherein the composition comprises a water-soluble polymer.

Chen does not disclose using cross-linked PVP. However, the use of cross-linked PVP is well known to drug formulation specialists who formulate omeprazole-containing compositions. The degree of cross linking affects the rate of dissolution. The drug formulation specialist of ordinary skill would have been motivated to use cross linked PVP to reduce the rate of dissolution.

The rejection is maintained.

◆

Claim 27 is rejected under 35 U.S.C. §103 as being unpatentable over Ballester Rodes (USP 5,626,875) in view of Lee (USP 6,228,400) or Bergstrand (WO 96/01623) or Lovgren (USP 4,786,505) or Henriksen (USP 6,391,342) or Chen (USP 6,096,340)

As indicated previously, Ballester Rodes discloses (e.g., col 2, line 13+) a composition comprising a neutral core to which is applied a mixture comprising omeprazole, followed by an intermediate layer, and a third layer. Ballester Rodes does not suggest using PVP. However, PVP is well known in the pharmaceutical formulation art, and is well known to be used in formulations that contain omeprazole. for example, each of the references cited in this Office action (Lee, Bergstrand, Lovgren, Henriksen, Chen) disclose pharmaceutical formulations that contain omeprazole and PVP.

Thus, the claim is rendered obvious.

❖

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.  
PRIMARY EXAMINER